

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant : Patrick Kennedy
Serial No. : 09/845,923
Filed : April 30, 2001
For : PHARMACEUTICAL COMPOSITION AND METHOD FOR
RELIEVING ITCH, PAIN AND SWELLING RESULTING FROM
INSECT BITES AND STINGS
Examiner : Patricia Leith
Art Unit : 1651

Declaration of Patrick Kennedy

I, Patrick Kennedy declare as follows:

1. I am the inventor of in the subject patent application.
2. My Educational background was primarily in sociology and geography, my employment background was concentrated in petroleum marketing. In 1999 my focus changed to an intensive research project, commissioned by American Natural Technology Sciences and centered on developing control agents for the red imported fire ant (RIFA or *Solenopsis invicta*). Under the resident tutelage of R H. Sparnicht, Ph.D. and the day to day guidance of John W. Kennedy (each highly credentialed, with an impressive life long resume in insecticide study), I began conducting field environmental impact studies to determine the effect the **Red Imported Fire Ant** (*Solenopsis invicta*) has had on humans, animals, beneficial insects, and the plant life in North Central Texas. In addition to the development of control products, the company's interests included studying the effects of the fire ant's sting on humans and animals. During the course of the study period, several personnel suffered the agonizing repercussions of the aggressive fire ants' venom. Fire ants are a growing health hazard and surveys have indicated that over 58% of the population living in infested areas is stung each year. Typical sting consequences include; burning pain, itching, subsequent blistering called "sterile pustules" and scarring. Many suffer more severe reactions such as hives and life threatening anaphylactic shock (more than 80

fatalities have been attributed to this ant). Further investigation revealed that the fire ants' sting is very toxic (aliphatic substituted alkaloids containing cytotoxic proteins, similar to snakes venom) and found to be more dangerous to humans than first suspected. The research was thus expanded to also include an examination of the effects of the fire ants' venom and means to counteract or relieve them. Microscopic analysis of the red imported fire ants' venomous stinger revealed that it is extremely small and that the ant must labor to pierce and pump it's venom into the skin, arching it's back while holding with its mandibles. This insight prompted me to begin researching a method to effectively remove and negate the venom before it enters the blood stream. When I had determined the final ingredients of the composition, Stephen Smith, Ph.D. (a well known formulating chemist) was employed to determine final formulation adjustments.

3. I have been employed in the field of mitigating insects and developing chemical and other compositions for mitigating insects for 5½ years.

4. I declare that the claimed composition is a composition able to mitigate the negative effects of insect bites.

5. The claimed composition consists of an effective amount of abrasive ingredient and a carrier, and that upon application of the composition, any of the itch, pain and swelling associated with an insect bite or sting is relieved.

6. While developing products, I have performed tests able to determine the efficacy of various compositions able to relieve the discomfort associated with insect bites and/or stings. Findings indicated that; properly applied, the formula can completely counteract and eliminate the discomforting effects of most insect toxins that distress the first few layers of the epidermis.

7. I have performed tests using the present claimed composition in order to relieve discomfort associated with fire-ant stings and that I have tested the claimed composition on my person and observed the use of the claimed composition on others.

8. During testing I have been bitten by and observed others being bitten by fire ants.

9. Shortly after being bit, the claimed composition was topically applied to the site of the bite.

10. Upon application, the site of the bite on both me and the subject(s) was noticeably healed and both I and the test subject indicated relief from the pain, itching and swelling caused by the bite.

11. My conclusions regarding the effectiveness of the claimed composition are supported by the statements contained in the testimonials attached hereto as Exhibit A.

12. All statements made herein to my knowledge are true. These statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under 18 U.S.C. 1001 and that such willful statements may jeopardize the validity of the Application or any patent issued thereon.



September 2, 2005

Patrick Kennedy

Date

EXHIBIT A

The Orange County Fire Ant Authority; (Richard A. Bowen (Program Manager), Orange County Fire Ant Authority, RIFA Eradication Division, Orange County Vector Control District

"Our fire ant field technicians come into contact everyday with these painful ants. We purchased 'Mitigator' for each technician and I hear positive reports everyday on how good the product works for relieving the pain associated with Fire Ant stings. Thanks!"

Mr. Charlie Cassidy (Field Operations Manager), Orange County Fire Ant Authority (OCFAA), Department of Agriculture, State of California

After having field tested Mitigator Sting & Bite Treatment, I called to purchase a supply for each of his field vehicles. Mr. Cassidy remarked, "**I am a very skeptical person but, this stuff really works**"! He was, in fact, so happy to find a product that really worked that, he submitted written testimonials on behalf of his field researchers as follows:

Brian McCarty – OCFAA Fire ant Technician

"I used Mitigator after being stung by red imported fire ants on the leg. The product relieved the pain and itching from the sting and there were no adverse effects the next day. The sting symptoms did not return, as they had in the past, using other products."

Cheri Miller - OCFAA Fire ant Technician

"I was stung on Friday, October 25, 2002. This morning, the sting was still bothering me. My ring would touch it and irritate it. After applying Mitigator, I was able to go through the day - even wear gloves – without further irritation. **Sure wish I had it earlier**"!

And the US Military - US Army MEDDAC (informal) Field Test/Testimonial

I am a Physician Assistant* assigned to the US Army MEDDAC, Ft. Leonard Wood, Missouri. I work at our troop medical clinic providing medical care for trainees assigned to Fort Leonard Wood. I was offered one box of Mitigator as a trial for our soldiers. I had divided the box in thirds, enough to cover one platoon in three different companies as they participated in their field training exercises. I asked the senior drill sergeant in each of these platoons to issue the Mitigator samples to their soldiers if they were being bitten by mosquitoes, bees, wasps, fleas, chiggers, gnats or ticks (after removal). I then asked for their feedback when they returned from the field. Each of the three senior drill sergeants reported that the Mitigator did make a substantial difference in the symptoms of pain and itching associated with insect bites and stings. This resulted in a vast decrease in sick-call visits during their FTX and recovery time. Worthy of note was the absence of side effects to any of the soldiers who tried this product. I'm not sure what the US Army could purchase this product for but if the price was right, this could be a valuable medication for all soldiers whom may come in contact with these pesky insects. *The PA's name has been omitted for security reasons.